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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,488	05/25/2001	Anthony E. Bolton	033136-179	4401

7590 05/06/2003

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EXAMINER
YU, MISOOK

ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 05/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/866,488	BOLTON ET AL.	
	Examiner	Art Unit	
	MISOOK YU, Ph.D.	1642	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 April 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): double patenting.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *19-30*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Misook Yu, 5-3-2003

Continuation of 5. does NOT place the application in condition for allowance because: Claims 19-30 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention and claims 19-30 also remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method of treating contact hypersensitivity (CHS), does not reasonably provide enablement for the purpose stated in the preamble of the claims for any other disease.

Applicant argues that the rejection under 35 U.S.C. 112, second paragraph should be dropped in view of amending claim 19 by adding CHS as a species of "T-cell-mediated or inflammatory diseases" but this argument is not persuasive because neither the specification nor applicant arguments in the prosecution history set reasonable boundary of what is being claimed for patent protection by the limitation. Applicant argued (see page 13 of Paper No. 8, amendment filed on 8-22-2002) that "endothelial dysfunction" and "T-cell-mediated or inflammatory disorders" are different disorders. However, atherosclerosis, inflammatory bowel disease, and graft versus host disease appear to be both "T-cell-mediated or inflammatory diseases" and "endothelial dysfunction" diseases. See the paragraph bridging pages 4 and 5 of Paper No. 11 for why the Office is confused about the metes and bounds of "T-cell-mediated or inflammatory diseases" recited in the instant claim 19.

As for the enblement rejection, applicant appears to argue that providing enablement for the full scope of the claimed method is not necessary because FDA monitors efficacy of a pharmaceutical. This argument is not convincing because the applicant's disclosure does not meet the enablement provision of 35 U.S.C. 112, first paragraph. The full scope of the instantly claimed method is prevention and treatment of notoriously difficult human diseases and the specification does not provide any in vivo model of any of the diseases except CHS. The art, for example, see Lui et al (copy provided with Paper No. 6, Human Immunology vol. 60, pages 568-74) recognizes a great deal of unpredictability in the treatment and/or prophylaxis of various diseases listed in the instant claim 19 because the diseases are not very well understood. The current state of art regarding treatment of autoimmune diseases and allograft rejection is still in research and development state. See the first sentence of Liu et al.

Applicant further argues the Office's enablement rejection is not supported by scientific literature shown in the four references presented as Exhibit B-E. This argument is not persuasive either because none of the references in Exhibit B-E teaches that the product used in the instantly claimed method can prevent or treat the diseases. The specification is limited to how to make and use apoptotic cells for treating mice with CHS, which is not a model for multiple sclerosis, rheumatoid arthritis, or any other disease listed in the instant claims. The specification does not provide adequate disclosure to enable skilled in the art to make and use the claimed invention without resorting to undue experimentation. The specification fails to teach how to make appropriate apoptotic cells capable of treating or preventing each of specific diseases in instant claim 19. Many of the diseases listed in claim 19 are notoriously difficult to treat. Considering the state of art for prevention and treating the diseases, it is maintained that one skilled in the art would have reasons to question the efficacy of the claimed treatment/prevention method in the absence of working examples or other evidence of the claimed method's effectiveness.

MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800 /600